K131385

5 510(k) Summary of Safety and Effectiveness Information

Submitter Information

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Date of Preparation:	June 5, 2013

SEP 27 2013

Device Name

Trade Name:	easy-graft™
Common/Usual Name:	Bone Grafting Material, Synthetic
Classification Name:	Bone Grafting Material (21 CFR 872.3930, Product code LYC)

Device Description

easy-graft™ contains:

- Syringe containing beta-tricalcium phosphate (β-TCP) granules coated with poly(lactide-co-glycolide) (PLGA)
- Ampule containing BioLinker™ (N-methyl-2-pyrrolidone and water)

easy-graft™ is a bioresorbable, synthetic, porous bone graft substitute. It consists of two components: granules (supplied in a syringe) and BioLinker™ (supplied in an ampule). After mixing the components together, easy-graft™ forms a moldable mass that can be applied directly from the syringe into the bone defect. easy-graft™ hardens in contact with body fluids, allowing a working time of approximately one minute after application into the bone defect. Depending on blood inflow, hardening may take longer.

easy-graft™ is provided in the particle sizes of 500 – 630 µm for smaller defects and 500 – 1000 µm for larger defects.

easy-graft™ is a biocompatible and osteoconductive material that allows for complete resorption by the body.

easy-graft™ can be used in combination with dental membranes.

easy-graft™ contains no animal or human derived substances. β-TCP and PLGA are derived from synthetic raw materials.

Intended Use/Indications:

easy-graft™ is indicated for the treatment of intraoral / maxillofacial osseous defects. Dental and maxillo-facial indications may include:

- Extraction defects (alveolar ridge preservation)
- Periodontal defects
- Peri-implant defects
- Augmentation of deficient alveolar crest (e.g. Guided Bone Regeneration, GBR)
- Sinus floor augmentation
- Defects after surgical extractions
- Defects after removal of bone cysts
- Defects after root resection or apicoectomy
- Defects after removal of autologous bone

Technological Characteristics Summary

Comparison to Predicate Devices

The predicate devices of easy-graft™ are:

- calc-i-oss™ bone graft substitutes (K042583) ("calc-i-oss"),
- Cerasorb® M Dental and Cerasorb® Perio (K051443) ("Cerasorb"),
- Bio-Oss®, Bio-Oss® Blocks and Bio-Oss® Collagen (K952618 / K970321 / K033815) ("Bio-Oss"),

- CalMatrix™ (K041324) ("CalMatrix"),
- Fortoss® Vital (K082383) ("Fortoss Vital")
- Atrisorb® Bioabsorbable Guided Tissue Regeneration (GTR) Barrier (K955838 / K982865) ("Atrisorb") and the
- Inion GTR™ Biodegradable Membrane System (K033074) ("Inion Membrane").

Predicate Device Comparison Table

Feature	Comparison
Intended Use	easy-graft™ is used in the same indications as the predicate devices. easy-graft™ and its predicate devices (calc-i-oss, Cerasorb, Bio-Oss and FortOss Vital) are intended to be used as a bone graft substitute for intraoral / maxillofacial osseous defects
Materials	easy-graft™ and the predicate devices calc-i-oss and Cerasorb are equivalent by using porous ß-TCP and conform to the standard specifications of ASTM F 1088-04a for a medical grade ß-TCP. easy-graft™ and the predicated devices Atrisorb and Inion Membrane use PLA polymers and N-methyl-2-pyrrolidone as a temporal plasticizer.
Form	easy-graft™ has the same handling properties as the predicate devices CalMatrix and Fortoss Vital (moldable, implant, hardening in the defect). easy-graft™ and the predicate device calc-i-oss are identical with regards to the shape and the size of the granules.
Porosity	easy-graft™ is porous like its predicate devices calc-i-oss, Cerasorb and BioOss.
Resorption / Bone Growth	easy-graft™ resorbs and is replaced with bone during the healing process like its predicate devices calc-i-oss, Cerasorb and FortOss Vital.
Mode of action	Newly forming autogenous bone tissue will grow into the pore volume of easy-graft™ and, in the course of material degradation, into the space previously occupied by easy-graft™. easy-graft™ displays the same mode of action as its predicate bone graft substitute devices (calc-i-oss, Cerasorb).

Risk Analysis and Test Methods:

The risks identified in the *FDA Guidance Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices (4/28/2005)* were addressed by the risk mitigation measures suggested therein as suggested in the following Table.

Risk Mitigation Measures

Identified Risks	Mitigation Measures
Ineffective Bone Formation	• Physical characterization according to *FDA Guidance Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices (4/28/2005)* • Chemical composition testing according to *FDA Guidance Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices (4/28/2005)* • Animal Testing • Labeling
Adverse Tissue Reaction	• Physical characterization according to *FDA Guidance Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices (4/28/2005)* • Chemical composition testing according to *FDA Guidance Class II Special Controls Guidance Document: Dental Bone Grafting Material Devices (4/28/2005)* • Biocompatibility in accordance with *#G95-1 (FDA Blue Book Memorandum, Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing).* • Animal Testing • Labeling
Infection	• Sterilization according to ISO 11137 (SAL < 10^{-6}) • Labeling
Improper Use	• Labeling

Summary of Nonclinical Testing

Chemical composition testing and physical characterization demonstrate the equivalence between easy-graft™ and its predicate devices. The results of the biocompatibility tests and the sterility testing conclude that easy-graft™ is biologically safe for its intended use. easy-graft™ and the predicate device Bio-Oss were compared in an animal implantation test. No significant differences were detected in terms of osseointegration of the material, bone formation, or defect bridging. Degradation of the graft particles of easy-graft™ was evident. Clinical case reports confirmed bone formation at the site of device application and degradation of the device. No new issues of safety or effectiveness were identified during the testing of the device.

Substantial Equivalence

The results of the chemical and physical characterization, biocompatibility and performance testing / evaluations demonstrate substantial equivalence of easy-graft™ to the predicate devices in intended use, technological characteristics and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

September 27, 2013

Degradable Solutions Ag
C/O Deborah Lavoie Grayeski
Senior Project Manager
M Squared Associated, Incorporated
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Alexandria, VA 22314

Re: K131385
Trade/Device Name: easy-graft™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: LYC
Dated: August 29, 2013
Received: August 30, 2013

Dear Ms. Grayeski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control, and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number: K131385

Device Name: easy-graft™

Indications for Use:

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- Defects after removal of autologous bone

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew J. Steen -S
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